Complete Summary

GUIDELINE TITLE

Guidelines of care for acne vulgaris management.

BIBLIOGRAPHIC SOURCE(S)

Strauss JS, Krowchuk DP, Leyden JJ, Lucky AW, Shalita AR, Siegfried EC, Thiboutot DM, Van Voorhees AS, Beutner KA, Sieck CK, Bhushan R, American Academy of Dermatology/American Academy of Dermatology. Guidelines of care for acne vulgaris management. J Am Acad Dermatol 2007 Apr;56(4):651-63. [180 references] PubMed

GUIDELINE STATUS

This is the current release of the guideline.

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

- October 6, 2006 – iPLEDGE: An update to iPLEDGE that will eliminate one element of the program.
- August 12, 2005 – iPLEDGE: Approval of a strengthened risk management program, called iPLEDGE, for Accutane and generic isotretinoin.

COMPLETE SUMMARY CONTENT

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SCOPE
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SCOPE

DISEASE/CONDITION(S)

Acne vulgaris

GUIDELINE CATEGORY

Evaluation
Management
Treatment

CLINICAL SPECIALTY

Dermatology
Family Practice
Internal Medicine
Pediatrics

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

To address the management of adolescent and adult patients presenting with acne but not the consequences of disease, including the scarring, post-inflammatory erythema, or postinflammatory hyperpigmentation

TARGET POPULATION

Adolescents and adults with acne vulgaris, i.e., open and/or closed comedones (blackheads and whiteheads) and inflammatory lesions including papules, pustules, or nodules

INTERVENTIONS AND PRACTICES CONSIDERED

Classification/Evaluation

1. Use of consistent classification/grading scale
2. Microbiologic testing
3. Endocrinologic testing

Therapy

1. Topical therapy
    - Retinoids
    - Benzoyl peroxide
    - Topical antibiotics (erythromycin and clindamycin)
    - Salicylic acid

    - Other topical agents
    - Combination topical agents
2. Systemic antibiotics
    - Tetracyclines (minocycline, doxycycline)
    - Macrolide antibiotics (erythromycin)
    - Trimethoprim-sulfamethoxazole
3. Hormonal agents
    - Estrogen-containing oral contraceptives
    - Anti-androgens (spironolactone, cyproterone acetate, and flutamide)
    - Oral corticosteroids
4. Isotretinoin
5. Miscellaneous therapy
    - Intralesional steroids
    - Chemical peels
    - Comedo removal
6. Complementary therapy
    - Herbal agents
    - Psychological approaches
    - Hypnosis/biofeedback
7. Dietary restrictions (not recommended)

MAJOR OUTCOMES CONSIDERED

- Usefulness, reliability, and sensitivity of acne severity grading scales
- Usefulness of endocrinologic and microbiologic testing
- Number of lesions
- Severity of lesions
- Psychological and emotional improvement
- Adverse effects of treatment

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

A work group of recognized experts was convened to determine the audience for the guidelines, define the scope of the guidelines, and identify nine clinical questions to structure the primary issues in diagnosis and management.

An evidence-based model was used and some evidence was obtained by a vendor using a search of MEDLINE and EMBASE databases spanning the years 1970 through 2006. Only English-language publications were reviewed.

NUMBER OF SOURCE DOCUMENTS

300

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus (Committee)
Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Evidence was graded using a three-point scale based on the quality of methodology as follows:

I. Good quality patient-oriented evidence
II. Limited quality patient-oriented evidence
III. Other evidence including consensus guidelines, extrapolations from bench research, opinion, or case studies

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

The available evidence was evaluated using a unified system called the Strength of Recommendation Taxonomy (SORT) developed by editors of the US family medicine and primary care journals (i.e., American Family Physician, Family Medicine, Journal of Family Practice, and BMJ-USA). This strategy was supported by a decision of the Clinical Guidelines Task Force in 2005 with some minor modifications for a consistent approach to rating the strength of the evidence of scientific studies.

For each intervention within the Clinical Questions, an effort was made to identify and present the best evidence regarding its use in the treatment of acne. Studies of clinical measurements of outcome were considered for analysis whether or not the clinical outcome was the primary outcome measured.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Clinical recommendations were developed on the best available evidence tabled in the guidelines and explained further in the companion document Guideline of Care for Acne Vulgaris Management, Technical Report.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

A. Recommendation based on consistent and good quality patient-oriented evidence.

B. Recommendation based on inconsistent or limited quality patient-oriented evidence.
C. Recommendation based on consensus, opinion, or case studies.

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

These guidelines have been developed in accordance with the American Academy of Dermatology (AAD)/American Academy of Dermatology Association "Administrative Regulations for Evidence-Based Clinical Practice Guidelines," which include the opportunity for review and comment by the entire AAD membership and final review and approval by the AAD Board of Directors.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Level of evidence grades (I-III) and strength of recommendations (A-C) are defined at the end of the "Major Recommendations" field.

I. Systems for the Grading and Classification of Acne
- Clinicians may find it helpful to use a consistent classification/grading scale (encompassing the numbers and types of acne lesions as well as disease severity) to facilitate therapeutic decisions and assess response to treatment.

Recommendation	Strength of Recommendation	Level of Evidence	References
Grading/classification system	B	II	Lehmann et al., 2002; Pochi et al., 1991; Doshi, Zaheer, & Stiller, 1997; Allen & Smith, 1982; Cook, Centner, & Michaels, 1979; Lewis-Jones & Finlay, 1995

II. Microbiologic and Endocrinologic Testing

Microbiologic Testing

- Routine microbiologic testing is unnecessary in the evaluation and management of patients with acne.
- Those who exhibit acne-like lesions suggestive of gram-negative folliculitis may benefit from microbiologic testing.

Recommendation	Strength of Recommendation	Level of Evidence	References
Microbiologic testing	B	II	Cove, Cunliffe, & Holland, 1980; Bojar et al., 1995; Eady et al., 1989; Harkaway et al., 1992

Endocrinologic Testing

- Routine endocrinologic evaluation (e.g., for androgen excess) is not indicated for the majority of patients with acne. Laboratory evaluation is indicated for patients who have acne and additional signs of androgen excess. In young children this may be manifested by body odor, axillary or pubic hair, and clitoromegaly. Adult women with symptoms of hyperandrogenism may present with recalcitrant or late-onset acne, infrequent menses, hirsutism, male or female pattern alopecia, infertility, acanthosis nigricans, and truncal obesity.

Recommendation	Strength of Recommendation	Level of Evidence	References
Endocrinologic testing	A	I	Lawrence et al., 1981; Lucky et al., "Predictors," 1997

III. Topical Therapy

- Topical therapy is a standard of care in acne treatment.
- Topical retinoids are important in acne treatment.
- Benzoyl peroxide and combinations with erythromycin or clindamycin are effective acne treatments.
- Topical antibiotics (e.g., erythromycin and clindamycin) are effective acne treatments. However, the use of these agents alone can be associated with the development of bacterial resistance.
- Salicylic acid is moderately effective in the treatment of acne.
- Azelaic acid has been shown to be effective in clinical trials, but its clinical use, compared to other agents, has limited efficacy according to experts.
- Data from peer-reviewed literature regarding the efficacy of sulfur, resorcinol, sodium sulfacetamide, aluminum chloride, and zinc are limited.
- Employing multiple topical agents that affect different aspects of acne pathogenesis can be useful. However, it is the opinion of the work group that such agents not be applied simultaneously unless they are known to be compatible.

Recommendation	Strength of Recommendation	Level of Evidence	References
Retinoids	A	I	Christiansen et al., 1974, Chalker et al., 1987; Shalita et al., 1999; Lucky et al., 1998
Benzoyl peroxide	A	I	Belknap, 1979; Schutte, Cunliffe, & Forster, 1982; Smith et al., 1980; Mills et al., 1986
Antibiotics	A	I	Bernstein & Shalita, 1980; Jones & Crumley, 1981; Prince et al., 1981; Lesher et al., 1985; Pochi et al., 1988; Dobson & Belknap, 1980; Mills et al., 2002; Leyden et al., 1987; Becker et al., 1981
Other agents	A	I	Zouboulis et al., 2000; Chalker et al., 1983; Tschen et al., 2001; Lookingbill et al., 1997; Hjorth & Graupe, 1989

IV. Systemic Antibiotics

- Systemic antibiotics are a standard of care in the management of moderate and severe acne and treatment-resistant forms of inflammatory acne.
- Doxycycline and minocycline are more effective than tetracycline, and there is evidence that minocycline is superior to doxycycline in reducing Propionibacterium acnes.
- Although erythromycin is effective, use should be limited to those who cannot use the tetracyclines (i.e., pregnant women or children under 8 years of age because of the potential for damage to the skeleton or teeth). The development of bacterial resistance is also common during erythromycin therapy.
- Trimethoprim-sulfamethoxazole and trimethoprim alone are also effective in instances where other antibiotics cannot be used.
- Bacterial resistance to antibiotics is an increasing problem.
- The incidence of significant adverse effects with antibiotic use is low. However, adverse effect profiles may be helpful for each systemic antibiotic used in the treatment of acne.

Recommendation	Strength of Recommendation	Level of Evidence	References
Tetracyclines	A	I	Smith, Chalker, & Wehr, 1976; Gratton et al., 1982; Blaney & Cook, 1976; Miller et al., 1996
Macrolides	A	I	Skidmore et al., 2003; Gammon et al., 1986; Christian & Krueger, 1975; Stoughton et al., 1980

Recommendation	Strength of Recommendation	Level of Evidence	References
Trimethoprim-sulfamethoxazole	A	I	Hersle, 1972

V. Hormonal Agents

- Estrogen-containing oral contraceptives can be useful in the treatment of acne in some women.
- Oral antiandrogens, such as spironolactone and cyproterone acetate, can be useful in the treatment of acne. While flutamide can be effective, hepatic toxicity limits its use. There is no evidence to support the use of finasteride.
- There are limited data to support the effectiveness of oral corticosteroids in the treatment of acne. There is a consensus of expert opinion that oral corticosteroid therapy is of temporary benefit in patients who have severe inflammatory acne.
- In patients who have well-documented adrenal hyperandrogenism, low-dose oral corticosteroids may be useful in treatment of acne.

Recommendation	Strength of Recommendation	Level of Evidence	References
Contraceptive agents	A	I	Lucky et al., "Effectiveness," 1997; Olson, Lippman, & Robisch, 1998; Thiboutot et al., 2001; Leyden et al., 2002
Spironolactone	B	II	Muhlemann et al., 1986
Antiandrogens	B	II	Greenwood et al., 1985; Miller et al., 1986
Oral corticosteroids	B	II	Nader et al., 1984

VI. Isotretinoin

- Oral isotretinoin is approved for the treatment of severe recalcitrant nodular acne.
- It is the unanimous opinion of the acne work-group that oral isotretinoin is also useful for the management of lesser degrees of acne that are treatment-resistant or for the management of acne that is producing either physical or psychological scarring.
- Oral isotretinoin is a potent teratogen. Because of its teratogenicity and the potential for many other adverse effects, this drug should be prescribed only by those physicians knowledgeable in its appropriate administration and monitoring.
- Female patients of child-bearing potential must only be treated with oral isotretinoin if they are participating in the approved pregnancy prevention and management program (iPLEDGE*).
- Mood disorders, depression, suicidal ideation, and suicides have been reported in patients taking this drug. However, a causal relationship has not been established.

*Because of the teratogenic effects of isotretinoin on the fetus, the FDA and the manufacturers have approved a new risk management program for

isotretinoin. Prescribers, patients, pharmacies, drug wholesalers, and manufacturers in the United States are required to register and comply with the iPLEDGE program. This program requires mandatory registration of all patients receiving this drug. Detailed information can be found on the iPLEDGE web site (www.ipledgeprogram.com).

Recommendation	Strength of Recommendation	Level of Evidence	References
Isotretinoin	A	I	Peck et al., 1982; Lehucher-Ceyrac & Weber-Buisset, 1993; Goulden et al., 1997; Strauss et al., "A randomized trial," 2001; McElwee et al., 1991; Strauss et al., "Safety," 2001; Dai, LaBraico, & Stern, 1992; Goldsmith et al., 2004; Rubinow et al., 1987

VII. Miscellaneous Therapy

- Intralesional corticosteroid injections are effective in the treatment of individual acne nodules.
- There is limited evidence regarding the benefit of physical modalities including glycolic acid peels and salicylic acid peels.

Recommendation	Strength of Recommendation	Level of Evidence	References
Intralesional steroids	C	III	Levine & Rasmussen, 1983; Potter, 1971
Chemical peels	C	III	Kim et al., 1999; Wang et al., 1997; Grimes, 1999
Comedo removal	C	III	Pepall, Cosgrove, & Cunliffe, 1991

VIII. Complementary Therapy

- Herbal and alternative therapies have been used to treat acne. Although these products appear to be well tolerated, very limited data exist regarding the safety and efficacy of these agents.

Recommendation	Strength of Recommendation	Level of Evidence	References
Herbal agents	B	II	Bassett, Pannowitz, & Barnetson, 1990; Paranjpe & Kulkarni, 1995; Lalla et al., 2001
Psychological approaches	C	III	Ellerbroek, 1973
Hypnosis/biofeedback	B	II	Hughes et al., 1983

IX. Dietary Restriction

- Dietary restriction (either specific foods or food classes) has not been demonstrated to be of benefit in the treatment of acne.

Recommendation	Strength of Recommendation	Level of Evidence	References
Effect of diet	B	II	Bett, Morland, & Yudkin, 1967; Fulton, Plewig, & Kligman, 1969

Definitions:

Levels of Evidence

I. Good quality patient-oriented evidence
II. Limited quality patient-oriented evidence
III. Other evidence including consensus guidelines, extrapolations from bench research, opinion, or case studies

Strength of Recommendations

A. Recommendation based on consistent and good quality patient-oriented evidence.
B. Recommendation based on inconsistent or limited quality patient-oriented evidence.
C. Recommendation based on consensus, opinion, or case studies.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

REFERENCES SUPPORTING THE RECOMMENDATIONS

References open in a new window

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate management of acne vulgaris

POTENTIAL HARMS

Topical Antibiotics

The use of topical antibiotics alone can be associated with the development of bacterial resistance.

Oral Antibiotics

- A major problem affecting antibiotic therapy of acne has been bacterial resistance, which has been increasing. Resistance has been seen with all antibiotics, but is most common with erythromycin.
- The use of oral antibiotics for the treatment of acne may be associated with adverse effects. Vaginal candidiasis may complicate the use of all oral antibiotics. Doxycycline can be associated with photosensitivity. Minocycline has been associated with pigment deposition in the skin, mucous membranes and teeth particularly among patients receiving long-term therapy and/or higher doses of the medication. Pigmentation occurs most often in acne scars, anterior shins, and mucous membranes. Autoimmune hepatitis, a systemic lupus erythematosus-like syndrome, and serum sickness-like reactions occur rarely with minocycline.

Hormonal Agents

- While flutamide can be effective, hepatic toxicity limits its use.
- Spironolactone may cause hyperkalemia, particularly when higher doses are prescribed or when there is cardiac or renal compromise. It occasionally causes menstrual irregularity.

Isotretinoin

- Oral isotretinoin is a potent teratogen.
- Side effects include those of the mucocutaneous, musculoskeletal, and ophthalmic systems, as well as headaches and central nervous system effects. Most of the adverse effects are temporary and resolve after the drug is discontinued.
- While hyperostosis, premature epiphyseal closure, and bone demineralization have been observed with prolonged use of higher dose retinoids, in the usual course of acne treatment these findings have not been identified. Therefore it is the unanimous opinion of the acne work group that routine screening for these issues is not required. Laboratory monitoring during therapy should include triglycerides, cholesterol, transaminase, and complete blood counts.
- Changes in mood, suicidal ideation, and suicide have been reported sporadically in patients taking isotretinoin. While these events have been seen, a causal relationship has not been established. Nonetheless, patients must be made aware of this possibility and treating physicians should monitor patients for psychiatric adverse effects.

Intralesional Steroids

Systemic absorption of steroids may occur. Adrenal suppression was observed in one study. The injection of intralesional steroids may be associated with local atrophy.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- Adherence to these guidelines will not ensure successful treatment in every situation. Furthermore, these guidelines should not be deemed inclusive of all proper methods of care or exclusive of other methods of care reasonably directed to obtaining the same results. The ultimate judgment regarding the propriety of any specific therapy must be made by the physician and the patient in light of all the circumstances presented by the individual patient.
- This report reflects the best available data at the time the report was prepared, but caution should be exercised in interpreting the data; the results of future studies may require alteration of the conclusions or recommendations set forth in this report.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Living with Illness

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Strauss JS, Krowchuk DP, Leyden JJ, Lucky AW, Shalita AR, Siegfried EC, Thiboutot DM, Van Voorhees AS, Beutner KA, Sieck CK, Bhushan R, American Academy of Dermatology/American Academy of Dermatology. Guidelines of care for acne vulgaris management. J Am Acad Dermatol 2007 Apr;56(4):651-63. [180 references] PubMed

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2007 Apr

GUIDELINE DEVELOPER(S)

American Academy of Dermatology - Medical Specialty Society

SOURCE(S) OF FUNDING

American Academy of Dermatology operational funds and member volunteer time supported the development of this guideline.

GUIDELINE COMMITTEE

American Academy of Dermatology Work Group
American Academy of Dermatology Clinical Guidelines Task Force

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Each of the following Work Group Members have served as a consultant, received research support or clinical research grants from the following companies:

Dr. Strauss was a consultant and investigator for Roche Laboratories receiving honoraria and grants, and a consultant for Medicis receiving honoraria.

Dr. Krowchuk has no relevant conflicts of interest to disclose.

Dr. Leyden was a consultant for Stiefel and SkinMedica, receiving honoraria; served on the Advisory Board and was a consultant for Galderma and Obaj, receiving honoraria; was on the Advisory Board and was a consultant and investigator for Connetics, Collagenex, Allergan, and Medicis, receiving honoraria.

Dr. Lucky was an investigator for Connetics, Dow, Galderma, Healthpoint, Johnson & Johnson, QLT, and Stiefel, receiving grants and an investigator and consultant for Berlex receiving grants and honoraria.

Dr. Shalita was a consultant, investigator, stockholder, and speaker for Allergan, receiving grants and honoraria; a consultant for Bradley/Doak receiving honoraria; served on the Advisory Board and was a consultant for Collagenex, receiving honoraria; was a consultant and investigator for Connetics receiving grants and honoraria; an Advisory Board member, consultant, investigator, and speaker for Galderma receiving grants and honoraria; a consultant, speaker, and stockholder for Medicis receiving honoraria; an Advisory Board member for Ranbaxy receiving honoraria; and a consultant, investigator, and speaker for Stiefel, receiving grants and honoraria.

Dr. Siegfried was an investigator for Atrix receiving salary.

Dr. Thiboutot served on the Advisory Board and was an investigator and speaker for Allergan and Galderma, receiving honoraria; was on the Advisory Board and was a consultant and investigator for Collagenex receiving honoraria; was on the Advisory Board and was an investigator for Connetics, Dermik, and QLT, receiving honoraria; and was a consultant, investigator, and speaker for Intendis, receiving honoraria.

Dr. Van Voorhees served on the Advisory Board and was an investigator and speaker for Amgen, receiving grants and honoraria; was an investigator for Astellas, Bristol Myers Squibb, and GlaxoSmithKline, receiving grants; was an Advisory Board Member and investigator for Genentech and Warner Chilcott, receiving grants and honoraria; was on the Advisory Board for Centocor receiving honoraria; was a speaker for Connetics receiving honoraria; and was a stockholder of Merck, owning stock and stock options.

Dr. Beutner was an employee of Anacor receiving salary and stock options and a stockholder of Dow Pharmaceutical Sciences receiving stock.

Ms. Sieck and Dr. Bhushan have no relevant conflicts of interest to disclose.

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from American Academy of Dermatology Association Web site.

Print copies: Available from the AAD, PO Box 4014, Schaumburg, IL 60168-4014, Phone: (847) 330-0230 ext. 333; Fax: (847) 330-1120; Web site: www.aad.org.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- Guidelines of care for acne vulgaris management. Technical report. American Academy of Dermatology Association. 2007. 69 p.

Electronic copies: Not available at this time.

Print copies: Available from the AAD, PO Box 4014, Schaumburg, IL 60168-4014, Phone: (847) 330-0230 ext. 333; Fax: (847) 330-1120; Web site: www.aad.org.

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI Institute on July 25, 2007. The information was verified by the guideline developer on August 2, 2007.

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